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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,698	09/21/2001	John J. Kilbane II	GTI-1464	4271
	7590 01/23/2004		EXAMINER MARSCHEL, ARDIN H	
Mark E. Fejer Gas Technology Institute 1700 South Mount Prospect Road Des Plaines, IL 60018			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/960,698

Applicant(s)

KILBANE, JOHN J.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 6 sheets
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Applicant's election of Specie B (Differential staining of microorganisms is required.) and Specie C (No microorganism growth required for microorganism to be identified) in the Paper filed 10/20/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The instant claims which correspond to the above elected species are instant claims 1-17 and 19-21 which therefore have been examined to the extent of the above specie elections.

### **VAGUENESS AND INDEFINITENESS**

Claims 1-17 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 cites the phrase "at least one DNA fragment" in lines 5, 7, and 8 which is reasonably interpreted as being directed to at least "one DNA fragment" molecule. It is well known that amplifying and cloning as cited in lines 5-7 of claim 1 may occur where only a single DNA fragment molecule is a starting material. The sequencing step, however, in lines 8-9 of claim 1 is not well known to result in detectable products that result in elucidating a DNA sequence. The specification utilizes both cloning and amplification in ways which correspond to utilizing as little as a single DNA fragment molecule, but the sequencing procedures as instantly filed is preceded either by amplification and/or cloning to give a significant number or amount of DNA so

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that well known sequencing procedures can give a sequence result. Thus, instant claim 1 is not commensurate in scope with the specification in that it is not limited to requiring that the sequencing step utilizes material, such as DNA, that first was either cloned or amplified. Claims which depend directly or indirectly from claim 1 are also rejected hereinunder due to their dependence. Clarification via clearer claim wording is requested.

Claim 5 is vague and indefinite because the "at least one universal primer" is required to have both a high-GC as well as a high-AT content which conflict in that nucleic acid sequences are one or the other but not both. Clarification via clearer claim wording is requested.

### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 8 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Short (P/N 5,958,672).

Short discloses the screening of clones produced from DNA from uncultivated microorganisms as summarized in the title and abstract. The disclosure of Short in columns 1-2 documents the DNA source microorganisms as being uncultivated and

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may have extreme growth condition requirements such as listed in column 2, lines 39-46. The microorganisms cited in Short also are disclosed as "non-culturable" in column 2, lines 57-60. Difficulty in obtaining pure cultures of such microorganisms is also described in column 1, lines 17-19, of the reference. These characteristics coincide with the characterization of unculturable microorganisms as set forth instantly in the instant specification on pages 2-3 and as cited in the instant claims. Libraries of DNA sequences from such non-culturable microorganisms are disclosed which are deemed DNA sequence databases as instantly claimed in the reference, for example, in column 4, lines 19-33, inclusive of being prepared via E.coli hosted cloning. Additional sequence databases for identifying clones with particular encoding is cited in the reference in column 7, lines 64, through column 8, line 7. Amplification of DNA by various means is cited in the reference in column 5, lines 19-31, including PCR. Staining of microorganisms for identification is disclosed in Short in column 13, line 42, through column 30, line 20, where various chemicals generate detectable signals via enzymatic activity. These disclosures anticipate the elected species of invention of instant claim 1, noting that no culturing is utilized in Short for microorganism identification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 2, 5-8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short (P/N 5,958,672); taken in view of Goh et al. (P/N 5,708,160).

Short has been summarized above as describing the basics of the instant invention directed to identifying microorganisms via sequences therein including amplification methodology, such as PCR. Protein or enzyme sequences are utilized in Short for such identification via database sequence comparison thus motivating and suggesting such sequence comparison utilizing PCR amplification, for example. Short, however, does not describe details of such amplification such as the use of a universal primer. Short describes heat shock protein for identification purposes in column 7, lines 3-7, which further motivates the practice of Goh et al. to improve the basic Short methodology with a specific protein analysis.

Goh et al. also is directed to specie identification of microorganisms (as in instant claim 8) wherein a protein sequence (responsive to heat shock, as a condition as in instant claim 16) is utilized for identification wherein the abstract summarizes the practice of the usage of a highly conserved region of a polypeptide. This is specifically referred to as a universal primer practice in column 1, lines 6-9, of the reference as also required in instant claim 2. Goh et al. also discloses the environmental source of microorganisms for identification in column 2, lines 41-45, as also the source of microorganisms described for the instant invention.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to identify microorganisms via protein sequence as in Short including motivating PCR practice wherein protein sequences are identified for

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microorganism identification by the use of universal primers thus resulting in the universal primer utilizing embodiments of the above listed instant claims. An exemplified primer set in Goh et al. is set forth in column 4, lines 25-29, which are high-GC content primers which reasonably is an option for instant claims 5 and 6. These primers are also randomly mixed and differ in DNA sequence as well as having a common length for optional primers therein as required in instant claim 7.

Claims 1, 3-8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short (P/N 5,958,672); taken in view of Hartley (P/N 5,043,272).

Short has been summarized above as describing the basics of the instant invention directed to identifying microorganisms via sequences therein including amplification methodology, such as PCR, but without specifics such as an arbitrary primer practice as in instant claim 3.

Hartley describes the generic amplification of any desired DNA sample via random primer usage. Such random primer practice (short etc. primers as in instant claims 4-7) is summarized in columns 2-3 as being universally useful in amplifying any DNA for later analysis as required in the Short description. This random and thus universal primer practice of Hartley is motivated for making the amplification of DNA via PCR generically useful without being limited as to source. Such random priming also will produce fragments from multiple loci as also required in instant claim 15.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to utilize the improvement of Hartley directed to random and arbitrary universal PCR priming in any desired method where amplification of DNA is



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desired as in the Short invention to result in the arbitrary primed amplification embodiments of the above listed instant claims.

### **INFORMATION DISCLOSURE STATEMENTS**

Enclosed are several sheets of PTO Form 1449. Two citations are lined through, referred to as U.S. Patent documents, due to citation numbering which is unrecognizable. These documents therefore could not be considered.

The Patent document of Short (P/N 6,280,926) is cited on the enclosed PTO Form 892 as being cumulative to the above Short (P/N 5,958,672) disclosure.

### **INFORMALITIES**

The disclosure is objected to because of the following informalities:

The BRIEF DESCRIPTION OF THE DRAWINGS section in the specification on page 8 does not summarize each separate drawing separately. In particular, there is no Figure 2 or 3 in the drawings, but rather Figures 2A – 2D and 3A – 3D.

In claim 2, line 2, the word "polymeric" appears to be misspelled because PCR is commonly known as "polymerase" chain reaction.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is



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(571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 20, 2004

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER